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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,092	01/08/2001	Michael J. Cima	10436-0009-999	5650

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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/756,092

Applicant(s)

Cima et al

Examiner

Maurie G. Baker, Ph.D.

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Jul 26, 2002

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-169 is/are pending in the applica

4a) Of the above, claim(s) 1-38, 47, 57, and 60-169 is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 39-46, 48-56, 58, and 59 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s). _____

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6

6) ☐ Other:

DETAILED ACTION

Please note: The number of Art Unit 1627 has been changed to 1639. Please direct all correspondence for this case to Art Unit **1639**.

1. The Response filed July 26, 2002 (Paper No. 11) is acknowledged. Claims 39, 43, 46, 49-50 and 52-53 were amended, and no claims were added or cancelled in this response.

Therefore, claims 1-169 are pending.

Election/Restriction

2. Applicant's election of Group III (claims 39-59) and election of species with traverse (in Paper No. 11) are acknowledged.

3. With respect to the restriction, applicant argues that "examination of claims 1-169 does not require separate or burdensome searches as alleged in the Office Action". The examiner respectfully disagrees. The detailed reasons for distinctness of each group was set forth in the Restriction Requirement (see paragraphs 2-12 of that action). Moreover, as also stated in the Restriction Requirement, the different inventions would require completely different searches due to their different classification and/or divergent subject matter and there is no expectation that the searches would be coextensive. Furthermore, art anticipating or rendering obvious each of the identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features

and/or characteristics. Each group could support a separate patent. Therefore, this does create an undue search burden. The requirement is still deemed proper and is therefore made FINAL.

4. Thus, claims 1-38 and 60-169 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions, the requirement having been traversed in Paper No. 11.

5. With respect to the species, the examiner maintains that the species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and would require different searches. For these reasons, the species election is maintained, for purposes of search.

6. However, applicant's arguments with respect to the modification for subgroups E and F of the species election and the other arguments with respect to sub-generic election (footnotes 2-4) were found persuasive. Thus, applicant's species election as presented in the Response is deemed to be fully responsive.

7. Please note MPEP § 803.02 with respect to species elections (emphasis added):

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. **The prior art search, however, will not be extended unnecessarily to cover all nonelected species.** Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the

Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

8. As at least some of applicants elected species were found in the art (with respect to various subgroups) as well as art that reads on the generic claim, claims 47 and 57 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected *species*, there being no allowable generic or linking claim. Note that the search has not been extended to all non-elected species.

9. Therefore, claims 39-46, 48-56, 58 and 59 are examined on the merits in this action.

Information Disclosure Statement

10. The Information Disclosure Statement (PTO-1449) filed June 20, 2002 is acknowledged; however, copies of the references cited therein are not in the file. The examiner is making efforts to locate these references; however, resubmission of these documents, if possible, by applicant would facilitate their consideration and would be greatly appreciated by the examiner. A signed copy of the PTO-1449 will be mailed as soon as the examiner obtains copies of the references. Please note that the other Information Disclosure Statement (filed June 4, 2001) has been considered and a signed copy of the PTO-1449 form is attached to this action.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent. Please see attachment.

12. Claims 39-41, 43-46, 48-52 and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Hol et al (US 6,267,935).

Hol et al disclose a method useful in the crystallization of proteins and other molecules using plates with a plurality of reservoirs and four sets of 48 different crystallization solutions (see Abstract, Figure 1 and Tables 1-4). The process of Hol et al permits “a large number of crystallization conditions to be easily and simultaneously tested in order to identify conditions under which a target molecule...can be crystallized” (column 3, lines 3-11). This reads directly on the claimed method where the “solid-forms” are crystalline materials (instant claim 44, 51 and 52). Hol et al discloses testing at least 24 conditions (see plate of Figure 1, also the four sets of 48 different crystallization solutions), which differ in their components and/or temperature, for example (see Tables 1-4 and column 9, line 54 through column 10, line 64). This reads on the limitations of instant claims 43, 49 and 50. The reference also discloses that other parameters can be varied, as needed for best crystal formation (see column 11, lines 21-33). The samples are examined for crystal formation via visual inspection or microscopy

(column 11, lines 8-20), reading on the limitations of instant claim 45. With respect to instant claim 46, Hol et al disclose harvesting crystals from the crystallization plate for x-ray diffraction analysis (column 11, lines 33-54). The reference discloses crystallization of five different proteins (see Examples 1-5) where samples are processed and crystals ("solid-forms") are detected in each. The proteins read on the claimed "pharmaceutical" (instant claims 48 and 55) as defined in the instant specification on page 15, lines 25-35. The reference discloses using amounts of protein in the 20-60 microgram range in the specific crystallization examples (Examples 1-5), reading directly on instant claims 40 and 41.

13. Claims 39, 43-46 and 48-56 are rejected under 35 U.S.C. 102(a) as being anticipated by Otsuka et al (Drug. Devel. Ind. Pharm. 1999).

Otsuka et al disclose a method for physiochemical characterization of glybuzole polymorphs (see Abstract, page 197). The process of Otsuka et al permits the systematic screening of polymorphic forms of a common drug (Abstract and Introduction, pages 197-198). This reads directly on the claimed method where the "solid-forms" are crystalline materials (instant claim 44, 51 and 52) and the "compound-of-interest" is a small molecule pharmaceutical (instant claims 48, 55 and 56). See also page 199 of the reference for sample amounts and aliquots (less than 1 gram is used in the aliquot for each test). Otsuka et al discloses testing at least 24 conditions (see Table 1 for 6 different crystallization methods and 11 different solvents used), which differ in their components and/or temperature and/or methodology, for example. This reads on the limitations of instant claims 43, 49 and 50. The samples are examined for crystal formation via visual

inspection or microscopy (page 199), reading on the limitations of instant claim 45. With respect to instant claim 46, Otsuka et al disclose x-ray diffraction analysis of the crystals (for example, column 1, page 199). The reference discloses that two different crystalline polymorphic forms are found (Form I and Form II – see Table 1 and pages 198-199, for example). This reads directly on the limitations of instant claims 51-54.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 39-46, 48-56, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Hol et al (US 6,267,935) or Otsuka et al (Drug. Devel. Ind. Pharm. 1999) as set forth above, in view of Stylli et al (US 5,985,214; of record).

The teachings of Hol and Otsuka are set forth supra.

The references lack the teaching of the specific numbers or amounts of compounds used in the method as set forth in instant claims 42, 58 and 59.

However, the optimization of such variables was well established in the art of high-throughput testing, see for example, Stylli et al in general and specifically columns 43 – 44 and 48 for teachings of numbers of samples tested, number per day and amounts.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use any of the methods of Hol or Otsuka for any number of samples and any amount of active component. One of ordinary skill would have been motivated to do so due in order to test a large number of samples and also optimize the method for the desired particular active ingredient.

Status of Claims/Conclusion

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the

organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
November 25, 2002

A handwritten signature in black ink, appearing to be 'MB' followed by a long horizontal stroke.

**MAURIE GARCIA BAKER, Ph.D.
PATENT EXAMINER**

Recent Statutory Changes to 35 U.S.C. § 102(e)

On November 2, 2002, President Bush signed the 21st Century Department of Justice Appropriations Authorization Act (H.R. 2215) (Pub. L. 107-273, 116 Stat. 1758 (2002)), which further amended 35 U.S.C. § 102(e), as revised by the American Inventors Protection Act of 1999 (AIPA) (Pub. L. 106-113, 113 Stat. 1501 (1999)). The revised provisions in 35 U.S.C. § 102(e) are completely retroactive and effective immediately for all applications being examined or patents being reexamined. Until all of the Office's automated systems are updated to reflect the revised statute, citation to the revised statute in Office actions is provided by this attachment. This attachment also substitutes for any citation of the text of 35 U.S.C. § 102(e), if made, in the attached Office action.

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 in view of the AIPA and H.R. 2215 that forms the basis for the rejections under this section made in the attached Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

35 U.S.C. § 102(e), as revised by the AIPA and H.R. 2215, applies to all qualifying references, except when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. For such patents, the prior art date is determined under 35 U.S.C. § 102(e) as it existed prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 prior to the amendment by the AIPA that forms the basis for the rejections under this section made in the attached Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

For more information on revised 35 U.S.C. § 102(e) visit the USPTO website at www.uspto.gov or call the Office of Patent Legal Administration at (703) 305-1622.